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Questions and answers on Sandostatin LAR and associated names (octreotide, 10, 20 and 30 mg powder and solvent for suspension for injection)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 26 June 2014, the European Medicines Agency completed a review of Sandostatin LAR. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Sandostatin LAR in the European Union (EU).

What is Sandostatin LAR?

Sandostatin LAR is a medicine that contains the active substance octreotide. Octreotide is a synthetic substance that mimics the activity of the natural hormone somatostatin. Like somatostatin, octreotide blocks the release of hormones found in the body, particularly growth hormone but also others such as thyroid-stimulating hormone (TSH) and various gut hormones. In Sandostatin LAR, octreotide is contained into microspheres that release the octreotide slowly over a few weeks, allowing the medicine to be given once a month.

Sandostatin LAR has been authorised in the EU since the 1990s for treating various conditions, including acromegaly (a disease in which the pituitary gland produces too much growth hormone, leading to excess growth of body tissues and organs) and gastro-entero-pancreatic endocrine tumours (tumours that arise from cells in the gut which release hormones that control various functions of the digestive system).

Sandostatin LAR is available as powder and solvent to be mixed to make a suspension for injection into a muscle. The medicine is marketed in all the EU Member States.

The company that markets these medicines is Novartis.

Why was Sandostatin LAR reviewed?

Sandostatin LAR is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of

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product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

Sandostatin LAR was identified as needing harmonisation by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

On 22 May 2013, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Sandostatin LAR in the EU.

What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

After reviewing the available data supporting the medicine's use, the CHMP agreed that Sandostatin LAR should continue to be used for the following conditions:

- Treatment of patients with acromegaly in whom surgery is inappropriate or ineffective, or in the interim period until radiotherapy becomes fully effective.
- Treatment of patients with symptoms associated with functional gastro-entero-pancreatic endocrine tumours.
- Treatment of patients with advanced neuroendocrine tumours of the midgut or of unknown primary origin where non-midgut sites of origin have been excluded.
- Treatment of TSH-secreting pituitary adenomas (benign tumours of the pituitary gland):
  - when secretion has not normalised after surgery and/or radiotherapy;
  - in patients in whom surgery is inappropriate;
  - in patients who have received radiotherapy, until the radiotherapy is effective.

4.2 Posology and method of administration

Having harmonised the indications, the CHMP also harmonised recommendations on the doses and duration of treatment. In addition, the CHMP recommended that Sandostatin LAR be given by deep injection into the gluteal (buttock) muscle.

4.3 Contra-indications

The CHMP agreed that hypersensitivity (allergy) to octreotide or any other ingredients in Sandostatin LAR should be the only contraindication.

Other changes

The CHMP also harmonised other sections of the SmPC including sections 4.4 (special warning and precautions for use), 4.6 (pregnancy and lactation) and 4.8 (side effects).

The amended information to doctors and patients is available here.

A European Commission decision on this opinion will be issued in due course.